Policy on C-CFR Publications

(Amended from June 2005 Publications Guidelines, Feb 2007)

I. INTRODUCTION

Background

The Breast and Colon Cancer Family Registries (CFRs) Program was established by the National Cancer Institute (NCI) in 1996 to facilitate interdisciplinary studies in the genetic epidemiology of cancer and to provide a flexible, comprehensive, and collaborative research infrastructure. The Colon CFR is made up of six recruitment (both clinic-based and population (registry)-based) centers and an Informatics Center. The recruitment centers are at the University of Hawaii, Honolulu, Hawaii; Fred Hutchinson Cancer Research Center, Seattle, Washington; Mayo Clinic, Rochester, Minnesota; University of Southern California, Los Angeles; University of Queensland, Brisbane, Australia; and Cancer Care Ontario, Ontario, Canada. The Informatics Center (IC) is currently at the Research Triangle Institute in North Carolina.

These C-CFRs systematically collect family history information, epidemiologic and clinical outcomes data, and related biological specimens from individuals with colorectal cancer and their families. Biospecimens, which include peripheral blood lymphocytes, plasma, and whole blood spots; EBV-transformed lymphocytic cell-lines (if available) tissue sections from paraffin-embedded colorectal cancers; fresh frozen tissue (if available); genomic DNA; and tumor-derived DNA, are collected, processed, and stored using standard protocols. These data and biospecimens are available to the scientific community at large through a process predicated on the establishment of collaborative studies that are subject to internal and external peer review. Additionally, the probands and their families are being actively followed in order to conduct prospective observational studies, as well as novel cancer prevention trials among high-risk family members.

C-CFRs Resources

As of December 31, 2006, the Colon CFR has collected the following data:

TABLE 3. Data and Biospecimen Collection by Ascertainment Source and Participant Type					
	Population-based Ascertainment		Clinic-based Ascertainment		Total
	Phase-I	Phase-II	Phase-I	Phase-II	Phase-I & II
CRC-Affected Proband					
with epidemiology data	5,111	2,141	441	448	8,141
with dietary data	2,613	946	186	171	3,916
with blood or mouthwash sample	4,661	1,852	450	415	7,378
with tumor block	4,391	1,131	406	383	6,311
with MSI results	3,635	25	285	66	4,011
with IHC results	3,636	534	321	325	4,864
Unaffected Proband					
with epidemiology data	N/A	N/A	145	83	228
with dietary data	N/A	N/A	134	53	187
with blood or mouthwash sample	N/A	N/A	142	117	259
CRC-Affected Relative					
with epidemiology data	533	132	516	143	1,324
with dietary data	267	43	377	68	755
with blood or mouthwash sample	425	126	506	132	1,189
with tumor block	433	100	596	149	1,278
with MSI results	267	1	473	32	773
with IHC results	297	63	465	87	912
Unaffected Relative					
with epidemiology data	12,332	2,923	3,273	1,288	19,816
with dietary data	6,051	1,078	2,328	760	10,217
with blood or mouthwash sample	5,913	2,539	3,053	1,233	12,738
Population-based Control					
with epidemiology data	3,754	354	0	0	4,108
with dietary data	2,193	0	0	0	2,193
with blood or mouthwash sample	2,431	301	0	0	2,732
Spouse Control					
with epidemiology data	720	68	195	0	983
with dietary data	358	65	0	0	423
with blood or mouthwash sample	688	70	200	0	958
Families with the following members all having blood in hand					
Affected proband with 1 unaffected sibling	993	460	141	95	1,689
Affected proband with 2+ unaffected siblings	629	302	185	92	1,208
Affected proband with 1 affected sibling	144	32	65	22	263
Affected proband with 2+ affected siblings	12	5	15	0	32
Unaffected proband with 1 affected sibling	0	0	32	15	47
Unaffected proband with 2+ affected siblings	0	0	13	0	13

Represents recruitment and data collection through December 31, 2006 (prepared 05 Apr 2007)
Ph-I – Phase I recruitment (1998-2002); Ph-II – Phase II recruitment (2002-2007)
In addition to paraffin-embedded tissue (PET), some C-CFR sites have been able to collect fresh frozen tissue during Phase II. To date, 250 fresh frozen tissues have been collected and stored.

II. PURPOSE.

One of the most important products of the Cancer Family Registries (CFRs) Program is timely publications that describe the CFRs, its procedures and data bases, and scientific findings resulting from the use of those data. Publications will be the main vehicle for disseminating findings to scientists and the public. Publications are also critical to the future funding of the CFRs and to the careers of those collecting the data. A large volume of high-quality publications is encouraged; recognizing that many scientists will be involved in the collection and use of the data, the following guidelines for publication and authorship have been developed.

The purposes of this policy are to:

- To document a Publication Policy for C-CFR Publications, defined as publications relating to activities funded by the National Cancer Institute (NCI) that describe or discuss creating, coordinating, setting policy and procedures for, and/or maintaining the C-CFR and its components.
- To state guidelines and procedures that are recommended for use in developing C-CFR publications and are consistent with the C-CFR principles of data sharing and collaboration.
- To provide practical and fair guidance for assigning authorship and acknowledgement that credit those who design, analyze and substantially participate in a study and the preparation of a publication or presentation;
- To ensure accurate reporting of the design, conduct, and analysis of studies, most of which will be collaborative and multi-disciplinary;
- To protect the confidentiality of medical and personal information in accordance with the Privacy Act and requirement for the protection of human subjects.

III. GUIDING PRINCIPLES:

The C-CFR Publication Policy is designed to advance and incorporate the following principles:

- Maintaining an inclusive stance on publications.
- Providing a process for developing publications that are consistent with C-CFR's initiatives, objectives, and priorities readily available to researchers.
- Requiring a central review process (involving the C-CFR Publications Working Group (PWG)) for all publications that will be acknowledged as C-CFR publications to ensure consistency and quality.
- Requiring that all contributors to a work intended for publication who have made contributions, consistent with the xxxx Authorship Guidelines, receive authorship credit.
- Fostering the careers of junior investigators with interests in the field of cancer research and related disciplines; wherever possible, younger and newer researchers should be encouraged to take a lead in C-CFR manuscript development and be acknowledged as lead authors whenever appropriate.
- Acknowledging that C-CFR is a large collaborative collection of projects involving a substantial number of researchers.
- Imposing an appropriately brief time period for review of publications.

IV. OWNERSHIP OF TOPICS

In any scientific collaboration a process is needed to determine who will take the lead to develop a topic or "own" it for the purpose of analyzing and publishing information. To help with this process the following matrix was developed with the assumption that all research and methodological publications or presentations utilizing the CFR fall into one of the following categories:

	CFR Investigators [a]	CFR Investigators & Institutional Collaborators [b]	CFR Investigators & External Collaborators [c]
Pilot Project [d]	☐	☐	☐
Core Project [e]	☐	☐	☐
New Project [f]	☐	☐	☐
Resource-Inspired Project [g]	☐	☐	☐

[a] Collaborators supported by the CFR award.
[b] Collaborators within the CFR-awarded Institution.
[c] Collaborators not supported by the CFR award and not within the CFR-awarded Institution.
[d] Either from core, supplemental, or non-CFR funds.
[e] Either original submission or competitive renewal.
[f] Collaborators supported by the CFR award but not funded by the core award.
[g] Topics related to methods or procedures, such as development of statistical, epidemiologic, or lab methods, pathology insights, etc.

Core Projects: Ownership of core projects being prepared for publication resides with the CFR Principal Investigator and the CFR Steering Committee (SC). Assignment of the relevant research area to specific Principal Investigators will be made by the CFR Principal Investigators as a group and require the majority vote for approval by the SC.

Pilot Projects and Resource-inspired projects: Ownership of these projects being prepared for publication is given to the CFR Investigator initiating the project.

New Projects: Ownership of new projects resides with the group that received approval from the Advisory Committee (AC) and SC to undertake the analysis. It is required that at least one CFR Investigator collaborates on the project and shares ownership of the manuscript.

V. DETERMINATION OF AUTHORSHIP

All persons designated as authors must "qualify" for authorship. Each author must have participated sufficiently in the work and take responsibility for the content. Modified from the Uniform Requirements for Manuscripts as submitted to Biomedical Journals by the International Committee of Medical Journal Editors (Ann Intern Med, 1988; 108:258-304), authorship credit should be based on substantial contributions to:

1. Conception and design or analysis and interpretation of data; and
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

All three conditions must be met. The collection of data and scientific status may also be considered in determining authorship listing. If the participation is solely in the acquisition of funding or the collection of data and is deemed not to justify authorship, those contributions should receive an acknowledgement in the paper (*see* Acknowledgements, below).

The procedural steps for determining final authorship of CFR publications are:

1. When a concept for a paper or series of papers is identified and introduced (be e-mail or in conferences or meetings) a lead author is identified according to the above discussion on ownership.
2. The lead author will circulate the concept of the paper to all Principal Investigators, the NCI Program Officer (and designee), and Principal Investigators for the Informatics Center (both University of California and Research Triangle Institute[1] and ask for a list of investigators who might be interested in the *opportunity to earn authorship.*
3. Each Principal Investigator will identify persons from his/her institution or affiliated institution that should be informed about the concept and have the opportunity to earn authorship, in the spirit of being over inclusive at this step.
4. The lead author will send the concept to all individuals identified as potential authors to ask if they are interested in the opportunity to earn authorship on the paper.
5. The lead author will maintain a list of interested authors and send them teleconference agendas, minutes, dummy tables, list of covariates, tables, drafts of the manuscript, and any related materials for their input.
6. At the end of the analytic and writing process each potential author will be asked if they feel they have earned co-authorship, using the Vancouver guidelines as a reference, but based on an academic honor system. Each potential author must complete and sign the authorship section, locate on the CFR publication checklist, explaining in what areas they have contributed to the manuscript (see attached).
7. The lead author has the right to question a claim for authorship.
8. The lead author will determine the order of listing all authors.
9. The lead author is responsible for collecting the signatures of all co-authors and finalizing the CFR publication checklist for submission to the chair of the Publications Working Group.

VI. ACKNOWLEDGEMENTS

At an appropriate place in the article (title-page foot note or appendix to the text; see the journal's requirement), abstract, poster or presentation, one or more statements should specify:

1. Scientific or other contributions that need acknowledging but do not justify authorship;
2. Acknowledgements for technical help;

[1] Note: The Research Triangle Institute functions as the Informatics Center for the CFR under a contract. Research activities that do not fall within the Scope of Work for the contract must be conducted outside of contract time. However, these research collaborations between the IC and the C-CFR Investigators for manuscripts are highly encouraged.

3. Acknowledgements of financial and material support, specifying the nature of the support;
4. Financial relationships that may pose a conflict of interest.

CFR Acknowledgements:

All ***core*** manuscripts, abstracts, posters and presentations must reference the Colon CFR in the title.

Multi-site **new project, pilot project,** and **resource-inspired project** manuscripts, abstracts, posters, and presentations whose subjects/samples include more than 50 percent CFR participants/samples should reference the Colon CFR in the title.

Financial acknowledgements:

All manuscripts, abstracts, posters and presentations shall acknowledge the federal funding of the CFR as follows:

"This work was supported by the National Cancer Institute, National Institutes of Health under RFA # CA-95-011 and through cooperative agreements with members of the Colon Cancer Family Registry and P.I.s. The content of this manuscript does not necessarily reflect the views or policies of the National Cancer Institute or any of the collaborating centers in the CFRs, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government or the CFR."

In addition, each CFR center providing data for the analysis should be acknowledged as:

"Australasian Colorectal Cancer Family Registry (U01 CA097735)"
"Familial Colorectal Neoplasia Collaborative Group (U01 CA074799)" [USC]
"Mayo Clinic Cooperative Family Registry for Colon Cancer Studies (U01 CA074800)"
"Ontario Registry for Studies of Familial Colorectal Cancer (U01 CA074783)"
"Seattle Colorectal Cancer Family Registry (U01 CA074794)"
"University of Hawaii Colorectal Cancer Family Registry (U01 CA074806)"
"University of California, Irvine Informatics Center (U01 CA078296)"

VII. PUBLICATION WORKING GROUP

The Publication Working Group (PWG), comprised of at least one investigator and one alternate from each CFR site and the NCI Program Officer and one designee, is a subcommittee of the SC, with members appointed by the SC, to develop and maintain these guidelines, to oversee all issues associated with publications, and to review all papers prior to submission for publication. This working group proposes recommendations to the SC for full committee vote as necessary, but otherwise represents the SC in matters dealing with publications.

VIII. REVIEW REQUIREMENTS

These guidelines assume that the named authors have all read and approved the manuscript before submission to the Publications Working Group review process. This policy pertains to tall manuscripts to be submitted for publication after the adoption of these publication guidelines (revision December 2006).

A. **Manuscripts**: All manuscripts will be submitted to the PWG Chair for review, as defined below, prior to submission for publication. The PWG Chair will assign the manuscript to a reviewer based on expertise in the subject matter. The review, designed to expeditiously assure and accurately report its design, conduct, and analysis, shall be completed within 15 days of submission to the PWG Chair.

A Colon CFR Manuscript Review Checklist will be completed by each reviewer, ensuring such items as:

- Appropriateness of title;
- Authorship representation;
- Whether CFR methods, procedures, and functions are correctly described.

B. **Abstracts, posters and presentations**: Abstracts may be submitted for publication without prior review. A copy of the abstract must be sent to the PWG Chair upon submission.

IX. PUBLICATION REQUIREMENTS

Upon publication or presentation, copies of all published manuscripts and abstracts and presented posters are to be submitted to the PWG Chair and the NCI Program Officer or designee. The NCI Coordination, Communication, and Administration Unit (CCAU) will distribute the published manuscript, abstract, or presentation to the CFR AC and SC, and to the Informatics Center (IC). The CCAU is responsible for adding all publications to the CFR publications list and entering the publication into the tracking database.

X. CONFLICTS & DISPUTES

A. Authorship: The principal author ultimately is in the position to make decisions regarding authorship. When a publication involves collaboration with multiple CFR sites, authorship and acknowledgement will be agreed upon by the collaborators . If there is still disagreement, the parties involved may seek help resolving such disputes with the help of the PWG and/or CFR SC, by providing a description of their role in the study and manuscript preparation.

B. Acknowledgement: The PWG Chairperson, on a case-by-case basis, will review disputes regarding acknowledgement of investigators or other personnel and institutions that made key contributions to the development of the publication.

C. Review process: The PWG Chairperson will resolve disputes with respect to the manuscript review process.

XI. PROCEDURES & RESPONSIBILITIES

It is the intent of the PWG that these guidelines provide streamlined procedures that ensure that credit is provided for those who design, analyze, and are major participants in a study or publication; that all publications utilizing CFR data are reviewed for accuracy; that all publications are tracked and catalogued; and that the responsibilities to accomplish these objectives are clearly delineated.

A. CFR Steering Committee Responsibilities:

1. Develop a CFR Publications Plan for timely reporting of study data;
2. Set priorities for CFR publications;
3. Resolve conflicts as necessary.

B. PWG Chair Responsibilities:

1. Act as the CFR liaison to the author;
2. Inform Informatics Center and PWG of the manuscript;
3. Assign a "CFR reviewer" based on expertise in the subject matter[2];
4. Provide feedback to the primary author (preferably within 15 days);

C. Lead Author Responsibilities:

1. Assume a leadership role in identifying co-authors, writing the paper, responding to reviewers' comments, corresponding with journal editors, and communicating with the PWG Chair;
2. Assign tasks, set deadlines, and assure that the tasks are completed on schedule;
3. Determine the authorship order for the paper in consultation with the other authors;
4. Complete and submit Section I of the CFR Manuscript Review Checklist to the PWG Chairperson (attached);
5. Submit a completed draft of the manuscript to the PWG Chairperson for review;
6. Incorporate feedback following internal CFR review and submit a final draft to the PWG Chairperson if required;
7. Obtain written permission from all persons acknowledged by name;
8. Submit the manuscript to the journal and send a hardcopy to the PWG Chairperson;
9. Make journal revisions;
10. Send a reprint or copy of published document to the PWG Chairperson and to the NCI Program Officer or designee.

D. CFR Reviewer Responsibilities:

1. Review manuscript;
2. Complete the *CFR Manuscript Review Checklist* (attached);
3. Provide scientific and editorial input as warranted;
4. Provide a copy of the completed checklist with Section III completed and other comments to the PWG Chair within 10 days.

E. NCI Associate Coordinator and Scientific Review Coordinator Responsibilities:

1. Receive the publication concept/proposal and enter it into a preliminary file for tracking purposes;
2. Track the publication, contacting the primary author after 6 months, if necessary;

[2] Reviewers are selected from the pool of C-CFR Steering Committee, Working Group, Subcommittee members and key project staff. Selection is based primarily on expertise in the subject matter. Reviewers can not be listed as an author.

3. Post the publication on the NCI's CFR web site and update the NCI web site of the actual publication and the specific citation;
4. Update the CFR publication list with final citation, link to the PubMed ID, and reference to the CFR project number.

XII. CONTACTS

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Colon CFR PWG Chairperson: John D. Potter, M.D., Ph.D. (jpotter@fhcrc.org)